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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,328	02/09/2000	Michael D. Macklin	7011-0032	3700

7590 01/15/2004

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/501,328

Applicant(s)

MACKLIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 50-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11July2003 has been entered. Claims 8, 16, 26, 30, and 42 have been amended.
2. Claims 1-8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-55 are pending. Claims 1-6 and 50-55 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a nonelected invention.
3. Claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 are under consideration.

Rejections/Objections Withdrawn

4. The objection to claim 26 is withdrawn in light of the amendment of the claim.
5. The rejection of claims 8, 16, 30, and 42, under 35 U.S.C. 112, second paragraph, indefiniteness, for "secondary composition", is withdrawn in light of the amendment of the claims.
6. The rejection of claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. 112, first paragraph, scope of enablement for eliciting an immune response in humans, is withdrawn.

Art Unit: 1645

7. The rejection of claims 8, 10, 11, 13, 16, 18, 19, 21, 30, 32, 33, 35, 42, 44, 45, and 47 under 35 U.S.C. 112, first paragraph, scope of enablement for boosting steps using secondary compositions, is withdrawn in light of the claim amendments.

Rejections Maintained

8. The rejection of claims 7, 8, 10, 11, 15, 16, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997), is maintained.

Applicants argue that Lowrie et al neither combined ≥ 2 antigens nor suggested that it be done, but is entirely silent on the idea of providing a vaccine composition containing multiple tuberculosis antigens. Instead, Lowrie et al showed that numerous single antigen vaccines provided "significant protection".

The examiner has considered applicants' argument, but does not find it persuasive. The claims do not restrict the number of antigens or DNAs except that the number is more than one, i.e., a "plurality". Thus, the statement of Lowrie et al does suggest a vaccine composition which contains a "plurality" of antigens, i.e., "only a few proteins".

Applicants argue that Lowrie et al never once considered the use of primary and secondary vaccine compositions.

The examiner has considered applicants' argument, but does not find it persuasive. The instant claims 7 and 15 do not recite any secondary composition or administration. Claims 8, 10, 11, 16, 18, 19 do recite administration of a "secondary" composition, of which one embodiment is that the secondary composition be the same as the primary composition. The claims do not recite any time limitation for the administration of the "secondary" composition. The instant specification teaches methods of eliciting immune responses in guinea pigs, i.e., Examples 2 and 3, by injecting a composition at 1 month, 2 months, and 3 months, with

Art Unit: 1645

challenge at 4 months. Lowrie et al also teaches the protocol by injecting a composition with multiple injections followed by challenge (Figure 2, legend, page 836), "Mice were immunized on four occasions at 3-4 wk intervals by injections of 50 µg plasmid DNA into each quadriceps muscle"....."Four weeks after the last DNA dose they were infected by i.p. injection with *M. tuberculosis*". Therefore, Lowrie et al does consider the use of primary (first immunization) and secondary (second, third, and fourth immunization) vaccine compositions.

9. The rejection of claims 23, 25-30, 32, 33, 37-42, 44, and 45 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997) in view of Sanford et al (U.S. Pat. No. 5,100,792), is maintained.

Applicants argue that the primary reference, Lowrie et al, fails to teach or suggest applicants' recited multiple antigen constructs and that Sanford et al does not provide the missing teaching or suggestion.

The examiner has considered applicants' argument, but does not find it persuasive. For discussion of Lowrie et al, see above. As stated in prior Office Actions, Sanford et al is utilized for teaching a transdermal delivery system utilizing a core carrier.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1645

12. Claims 8, 10, 11, 13, 14, 16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly amended claims 8, 16, 30, and 42 now recite that the secondary composition contains ≥ 1 DNA encoding a plurality of antigens or "said plurality of *M. tuberculosis* antigens in peptide or protein form". It is unclear what are the metes and bounds of said "peptide or protein form". For instance, does "form" mean that the antigens are entire antigens, fragments thereof, or possibly fusion proteins?

Claims 10, 11, 13, 14, 18, 19, 21-29, 32, 33, 35-41, 44, 45, and 47-49 depend from these claims but do not correct the indefiniteness.

Conclusion

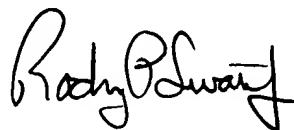
13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645
January 13, 2004